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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,085	01/09/2002	Patricia Lynne Conway	28053/38258	6842

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EXAMINER	
AFREMOVA, VERA	
ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 05/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,085	CONWAY ET AL.	
	Examiner	Art Unit	
	Vera Afremova	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 February 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-41 and 63-153* is/are pending in the application.

4a) Of the above claim(s) *20-40 and 63-75* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *76-153* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/25/2005*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 41 and 76-153 are under examination.

Claims 20-40 and 63-75 were withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected subject matter. Election was made without traverse [3/03/2003]. Claims 1-19 and 42-62 were cancelled by applicants [10/27/2003].

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 41, 76, 77, 79, 81, 88, 90-105, 109-120, 124-135 and 139-150 remain rejected under 35 U.S.C. 102(b) as being anticipated by US 5,143,845 (Masuda) as explained in the prior office action.

Claims are directed to a microbial product comprising one component such as "harvested microbes" or grown/cultured microbes that have improved characteristics associated with survival/recovery. Some claims are further drawn to incorporation of microbial products into various food, feed, pharmaceutical and bioremediation products suitable for delivery of viable microbes. Some claims are further drawn to the use of microbes including representatives of the genera *Lactobacillus*, *Bifidobacterium, Clostridium, Bacillus*, etc. in the microbial products.

The cited patent is relied upon as explained in the last office action and repeated herein.

US 5,143,845 discloses a microbial product comprising harvested or cultured microbes having improved characteristics or a microbial preparation comprising live symbiotic mixture of bacteria (see abstract). The microbial preparations are incorporated into a pharmaceutical product comprising potato starch (col. 2, lines 45-46 or col. 3, lines 16-25) and/or into other food or feed

products suitable for delivery of the live probiotic microorganisms (col. 1, line 39-40) including fluid-based products (col. 7, line 17) and/or milk derivative or milk casein containing products (col. 5, line 52). The microbes were cultured and harvested before incorporation into the products (example 2) and, thus, they are "harvested" or cultured, activated and proliferated. The cited patent teaches that the resulting microbial preparations are capable to effectively proliferate (col. 4, lines 18), that they demonstrate satisfactory effects upon administration as related to maintenance and recovery in the digestive tract (col. 3, lines 65-68) and that they are characterized by heat stability, dry stability and drug stability (col. 2, lines 53-55). Thus, the activated microbial preparation of the cited patent are characterized by an increased survival/recovery rate and they are substantially unaffected by stresses within the meaning of the instant claims. The microbial products of the cited patent include representatives of the genera *Lactobacillus*, *Bifidobacterium, Clostridium, Bacillus* and others (col. 2, lines 34-44) as the microbial preparations of instant claims 96-99, 111-114, 126-129, and 141-144.

Therefore, the cited patent US 5,143,845 discloses identical composition comprising microbial preparations characterized by increased survival, viability and recovery as required for the claimed product. Thus, the cited patent US 5,143,845 anticipates the presently claimed invention.

Claims 41 and 76-153 remain rejected under 35 U.S.C. 102(b) as being anticipated by US 6,060,050 (Brown et al.) in the light of evidence by US 5,714,600 (McNaught et al.) as explained in the prior office action.

Claims are directed to a microbial product comprising one component such as "harvested microbes" or grown/cultured microbes that have improved characteristics associated with survival/recovery. Some claims are further drawn to incorporation of a second component such as resistant starch into the total microbial products, to the amounts of resistant starch in the total microbial products such as 0.1-90 % (w/) or about 10% (w/w). Some claims are further drawn to the use of various forms of resistant starch in the total products including resistant starches derived from maize, rice, barley, potatoes and resistant starches having amylose content at least 70 %, 80% or 90%. Some claims are further drawn to incorporation of microbial products into various food, feed, pharmaceutical and bioremediation products suitable for delivery of viable microbes. Some claims are further drawn to the use of microbes including representatives of the genera *Lactobacillus*, *Bifidobacterium, Clostridium, Bacillus, Saccharomyces, Clostridium, etc.* the microbial products.

The cited patent is relied upon as explained in the last office action and repeated herein.

US 6,060,050 teaches a microbial preparation comprising harvested microbes with improved characteristics associated with survival/recovery in intestinal tract and it teaches incorporation of resistant starch into microbial preparations and/or into products with microbial preparations (col. 1, lines 55-65). The cited patent discloses amounts of resistant starch in the product and/or in the microbial preparations such as 2-20 % w/w (col. 2, lines 57-58) or 10% (col. 8, lines 15-25). The cited patent teaches the use of resistant starch RS1, RS2, RS3 or RS4 (col. 1, line 54) which is derived from maize, rice, barley, potatoes (col.4, lines 3-5) and to the use of maize resistant starch with amylose content of more than 50% or more than 80% (col. 3, lines 62-65). The phrase "more than" as related to the amylose content means "at least 90% "

because the cited US 6,060,050 refers to the use of maize resistant starch disclosed in WO94/03049, which is now US 5,714,600, wherein the maize resistant starch having more than 80% of amylose include amylose contents of "at least 90% " (see US 5,714,600 col. 2, line 67). The resistant starch in the products of US 6,060,050 are also chemically or physically treated starches by chemical modification including esterification, acidification, etc. (col. 4, lines 15-21). The cited US 6,060,050 also teaches that microbes were cultured or grown on resistant starch containing media (col. 5, lines 31-36; col. 9, lines 50-55 and table 4) in order to select probiotic microorganisms that can grow on resistant starch (col. 2, lines 14-17) and to survive in the intestinal tract (col. 1, line 63-64). The microbes in the products of US 6,060,050 are characterized by a stress resistance including resistance to freezing and to freeze-drying (col. 2, line 50). The cited patent discloses to the use of various microorganisms including *Lactobacillus*, *Bifidobacterium, Clostridium, Bacillus, Saccharomyces, Clostridium* in the microbial products (col. 2, lines 20-25) and incorporation of microbial products into various food, feed, pharmaceutical and bioremediation products suitable for delivery of viable microbes (col. 4, lines 55-60). Thus, the cited patent US 6,060,050 anticipates the claimed invention.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 41 and 76-153 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,143,845 (Masuda) taken with US 6,060,050 (Brown et al.), Brown et al. (IDS reference # 6; "High amylase maize starch as a versalite prebiotic for use with probioitc bacteria". Food

Australia 50 (12), December 1998) and US 5,714,600 (McNaught et al.) as explained in the prior office action.

Claims as explained above.

The cited references are relied upon as explained in the last office action and repeated herein.

US 5,143,845 is relied upon as explained above for the disclosure of microbial products characterized by increased survival and recovery. US 5,143,845 is lacking particular disclosure about the use of resistant starch in the total product.

However, US 6,060,050 teaches microbial products comprising microbes and various forms resistant starch.

Further, the reference by Brown et al. is relied upon for the teaching directed to beneficial properties of resistant starch and to a clear suggestion to incorporate resistant starches into microbial preparations/products for improving robustness and viability of probiotics in gastrointestinal tract and in the food products (table 2). It is also teaches that the high amylose maize resistant starch is particularly beneficial for lactic acid bacteria because it enhances bacterial survival and stress resistance (page 607, col. 1).

The cited patent US 5,714,600 is relied upon to demonstrate that physically and/or chemically modified resistant starch (col.7, lines 13-15) including maize starch having high amylose contents of at least 40-90% (col.2, lines 63-67) are available in the prior art and they have been suggested for various compositions including foods and other industrial products (col. 1, line 24).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify compositions of US 5,143,845 by incorporation of maize resistant starch of US 6,060,050 or of US 5,714,600 with a reasonable expectation of success in increasing survival and recovery of microbial preparations in various products because benefits of incorporations of resistant starch into probiotic compositions are known as adequately demonstrated by Brown et al. One of skill in the art would have been motivated to use high amylose maize resistant starch in microbial preparations/products for the expected benefits related to the improved viability and to stress resistance of probiotic cultures {Brown et al.}. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented be the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321© may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground

provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 41 and 76-153 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,221,350 (Brown et al.).

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are both directed to microbial probiotic products comprising microorganisms and resistant starch.

Claims of US 6,221,350 appear to be narrower and they require 3 components in the product including microorganisms, resistant starch and oligosaccharide. Some of the claims of the instant application are broader and they are drawn to generic microbial products, for example: claims 41, 77, 79, 81, or 88. However, some of the claims of the instant applications are drawn to products comprising both microorganisms and resistant starch, for example: claims 78, 80, 82-87, 89, 106-108, 121-12, 136-138 and 151-153. The microorganisms in the compositions of the instant application and of the cited patent are identical, for example: see patented claims 3-6 and see instant 96-99, 111-114, 126-129 and 141-144. The resistant starch in the compositions of the instant application and of the cited patent is identical, for example: see patented claims 9-12 and instant claims 83-87. Although the claims of the instant application are not clearly directed to the use of oligosaccharides, they encompass the use of food products

including confectionary, biscuits, desserts or flavored drinks that do not exclude the use of oligosaccharides or fructo-oligosacharides and, therefore, are reasonably expected to comprises at least some amounts of oligosaccharides or fructo-oligosacharides.

Accordingly, the claimed compositions are obvious variants. Thus, the inventions as claimed are co-extensive.

Response to Arguments

Applicants' arguments and Declaration by Ian Brown filed on 2/25/2005 have been fully considered but they are not found persuasive.

A. With regard to US 5,143,845 (Masuda) applicants' main arguments and contents of Declaration are drawn to the idea that the potato starch-containing medium was sterilized by autoclave and, thus, there was no resistant starch in the microbial culture media for growing and making microbial preparations (response pages 15-16, Declaration and related exhibits).

However, the rejection over US 5,143,845 (Masuda) is only applied to the claims drawn to microbial preparations but not to the claims drawn to composition comprising microbial preparation plus resistant starch.

The presently claimed product is defined as a product-by-process. The product-by-process claims are not limited to the manipulations of the recited steps, only to the final structure of the product obtained and the patentability of a product does not depend on its method of production. MPEP 2113. In the instant claims, the final product or final microbial preparation is said to be relatively better over some generic starting microbial cells with respect to microbial survival and recovery. However, neither starting nor end products are particular microbial strains that are available, reliable and characterized by some particular rates of survival or recovery.

Thus, in view of a relative characterization that is defined by the structure of the instant claims, the claimed microbial product *per se* has only one final physical or measurable feature such as viability or capability to survive and/or recover. Therefore, the cited "microbial preparation having increased survival /recovery rate" disclosed by US 5,143,845 (Masuda) that is characterized as having enhanced heat, dry and drug stability, that is stress resistant, that is capable to grow on starch or on cooked potato starch and that is taught as suitable for pharmaceutical and food products is within the scope of the claimed product.

Furthermore, regardless the fact that different forms of resistant starches are encompassed as substrates for growing and/or adapting microbes by the process steps in the product-obtained-by-process, the end microbial products are no more than viable microbial compositions capable to survive and to recover. Thus, although US 5,143,845 (Masuda et al.) might not use resistant starch and/or various categories of resistant starch for making and harvesting microbes, this fact cannot distinguish between structural and/or material differences of the claimed final product over the final product of US 5,143,845 (Masuda et al.) for generic microbes as claimed.

B. With regard to the claim rejection over US 6,060,050 {Brown et al.} applicants argue that the microbes in the product the cited patent are not harvested after culturing on a resistant starch but after culturing in a conventional medium or by conventional means (response page 17, par. 1). This is not found persuasive because the cited patent teaches microbial preparations grown on resistant starch, for example: see col. 5, lines 32-36 or figures 9 and 10. Applicants argue that figures 9 and 10 depict the in vitro growth profiles that are lacking "harvested" microbial preparations. This is not found persuasive because figures depict cells number and, thus, cells

were harvested and counted. Further, even though the cited patent does not clearly discloses active step of comparing starting and end microbial products, the final microbial product as disclosed by the cited patent is clearly said to comprise two components including viable microbes and resistant starch as required for the presently claimed product. Thus, the disclosed product is within the scope of the claimed product.

In response to applicant's argument that the microbes of US 6,060,050 were grown on resistant starch for a different purpose that is demonstrate that resistant starch can be used as substrate for microbial growth (response page 17, par. 3), it is noted that a recitation of the intended use or effects of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). The instant claims are drawn to a product comprising two components that are 1) microbes with "increased" capability to survive on resistant starch and 2) resistant starch. The structure of the prior art is a composition comprising 1) microbes capable to utilize resistant starch and 2) resistant starch. Thus, the prior art structure is identical to the structure of the claimed product. Therefore, the prior art structure meets the claim.

Applicants' argument that the cited patent does not discloses combining resistant starch with microbes that were grown on resistant starch (page 18, par. 3) relates to a method of making product. The product US 6,060,050 demonstrates a composition comprising microbes grown on resistant starch and resistant starch.

C. With regard to the claim rejection over references US 5,143,845 {Masuda et al.} in view of Brown et al. and US 5,714,600 {McNaught et al.} applicants argue that the prior art is lacking suggestion that culturing on resistant starch would provide microbes with advantages related to growth or survival rates (response pages 18-19). This is not found persuasive because the reference by Brown et al. (IDS reference #6) clearly teaches beneficial properties of resistant starch including improved robustness of probiotic cultures, improved viability of probiotics, enhanced survival/proliferation rates, etc. (table 2). The cited references adequately demonstrate suggestion and motivation to combine resistant starch and viable microbial preparations as explained above and they also demonstrate availability of different forms of resistant starches.

D. With regard to the obviousness-type double patenting rejection applicants' arguments (response page 19) are not found persuasive because they are directed to the differences in the intended use of resistant starch in the compositions comprising microbes and resistant starch. Applicants argue that resistant starch in the claims of US 6,221,350 is a carrier and is not used as a substrate to select or to harvest microbes having "increased" recovery/survival rates. However, microbes in the claims of US 6,221,350 (claim 5, for example) belong to the same species as the microbes in the instant claims (claim 96, for example). Moreover, US 6,221,350 discloses that the probiotic microbes of the claimed invention are selected such that they are able to utilize starch as nutritional source (col. 2, lines 36-40). Thus, the claimed inventions are obvious variants.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached at (571) 272-0926. The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova,

AU 1651

May 26, 2005

V. Afremova

VERA AFREMOVA
PRIMARY EXAMINER